

REMARKS

Claims 1-18 and 26 were pending in the application. Claims 1-5 have been canceled without prejudice, and claims 6-10 and 26 have been amended. Accordingly, upon entry of the amendments presented herein, claims 6-18 and 26 will remain pending in the application.

Support for the amendments to the claims may be found throughout the specification and claims as originally filed. *No new matter has been added by the foregoing claim amendments.*

Any amendments to and/or cancellation of the claims are not to be construed as an acquiescence to any of the rejections set forth in the instant Office Action, and were done solely to expedite prosecution of the application. Applicants hereby reserve the right to pursue the subject matter of the claims as originally filed in this or a separate application(s).

Withdrawal of Certain Objections/Rejections

Applicants gratefully acknowledge the Examiner's indication that the following objections/rejections have been withdrawn:

- a) the previous objection to the specification as "failing to provide proper antecedent basis for the claimed subject matter";
- b) the previous objections to claims 17, 18, and 19;
- c) the previous rejection of claims 19-25 under 35 U.S.C. § 102(b) as being anticipated by Turk *et al.* ((1999) *Chem. Biol.* 6:823-833);
- d) the previous rejection of claims 1-17 and 19-25 under 35 U.S.C. §103(a) as being unpatentable over Turk *et al.* ((1999) *Chem. Biol.* 6:823-833) and Amitai *et al.* (WO 02/065977); and
- e) the previous rejection of claims 1-17 and 19-25 under 35 U.S.C. §103(a) as being unpatentable over Griffiths, *et al.* ((1998) *Proc. Natl. Acad. Sci., USA*

95:15183-15188) and Morain *et al.* ((2000) *Br. J. Clin. Pharmacol.* 50:350-359).

Previous Grounds of Rejection

Rejection of Claims 1-3, 9, and 10 Under 35 U.S.C § 112, Second Paragraph

The Examiner has maintained the rejection of claims 1-3, 9, and 10 under 35 U.S.C. § 112, second paragraph, as allegedly “being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” In particular, the Examiner is of the opinion that

[i]t is unclear as to which test compound or biological target to use for the method of measuring the ability of a test compound to inactivate a biological target in the instant claims 1-3, 9, and 10. The administration of different compound will vary with regards to dose or the biological target of interest.

Applicants respectfully traverse this rejection on the grounds that the claims are clear and definite. However, without acquiescing to the validity of the Examiner’s rejection and solely in the interest of expediting prosecution and allowance of the pending claims, Applicants have canceled claims 1-3, from which claims 9 and 10 depend, thereby rendering the foregoing rejection moot. Accordingly, Applicants respectfully request that this rejection of claims 1-3, 9, and 10 under 35 U.S.C. §112, second paragraph be reconsidered and withdrawn.

New Grounds of Rejection

Rejection of Claims 1-18 and 26 Under 35 U.S.C § 112, Second Paragraph

The Examiner has rejected claims 1-18 and 26 under 35 U.S.C. § 112, second paragraph, as allegedly “being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” In particular, the Examiner is of the opinion that

[i]t is unclear as to what parts of a biological sample constitutes “fractions thereof” or “portions thereof”. Also the necessary structural/physical characteristics of the fraction or portions of the biological sample, such as whole cell or individual cell components to carry out the invention of the instant claims are not provided.

Applicants respectfully submit that the amendments to the claims presented herein render this rejection moot. These claim amendments should not be construed as an acquiescence to the Examiner’s rejection and were done solely in the interest of expediting prosecution and allowance of the pending claims.

Notwithstanding the foregoing, Applicants wish to make the following remarks of record. Applicants respectfully traverse this rejection and submit that, based on the teachings in the specification and the common meaning of this term in the art, one of skill in the art would find the terms “portion thereof” and “fraction thereof” to be clear and definite and to mean less than the whole. Specifically, the term “portion” is defined in Webster’s Dictionary as meaning a “limited part of the whole” (see relevant excerpt from Webster’s Dictionary 10th edition, attached herein as Appendix A). Moreover, at page 10, lines 19-35, the specification teaches that the terms “portion thereof” and “fraction thereof” include, for example, various cell types that can be isolated from a whole blood sample, a tumor, or cells that can be, for example processed by, for example, homogenization of a tissue sample. Finally, as evidenced by a plethora of issued U.S. patents containing these terms in the issued claims (examples of which are attached herein as Appendices B and C¹) these terms were accepted by the U.S. Patent and Trademark Office to be clear and definite. Based on all of the foregoing, it is evident that the terms “portion thereof” and “fraction thereof” would be clear and definite to one of skill in the art and understood to mean less than the whole. Accordingly, Applicants respectfully request that this rejection of claims 1-18 and 26 under 35 U.S.C. §112, second paragraph be reconsidered and withdrawn.

¹ See, e.g., claims 1-6 of Appendix B and claim 34, step (c), claim 40, step (c), claim 44, step (d), claim 50, step (d), claim 54, step (b), and claim 98, step (d) of Appendix C.

The Examiner has also rejected claims 3 and 7 under 35 U.S.C. § 112, second paragraph, as allegedly “being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” In particular, the Examiner is of the opinion that

[i]t is unclear as to what constitutes a “saturating amount” as there are multiple levels/definitions of saturation, such as saturated to the point in which a solution can dissolve no more of a substance, supersaturation where the concentration of a substance in a solution is higher than the saturation point and in biochemistry saturation refers to the fraction of total protein binding sites that are occupied at a given time.

Applicants respectfully traverse this rejection and submit that, based on the teachings in the specification and the knowledge generally available to one of skill in the art at the time of filing, the term “saturating amount” would be clear and definite to the skilled artisan. More specifically, Applicants submit that at, for example, page 9, line 28, through page 10, line 11, the specification expressly defines a “saturating amount” as

an amount of a compound which is in excess, on a per mole basis, relative to a specified reaction partner. For example, an irreversible quantifiable MetAP-2 inhibitor is present in a saturating amount if it is present in molar excess over the anticipated amount of free MetAP-2. The irreversible quantifiable MetAP-2 inhibitor can, for example, be present at a 1.1- to 10-fold molar excess over the anticipated amount of free MetAP-2. The anticipated amount of free MetAP-2 can, for example, be determined using the amount of MetAP-2/inhibitor complex formed in a control sample. Alternatively, the irreversible quantifiable MetAP-2 inhibitor can be titrated, with the amount of MetAP-2/inhibitor complex determined as more inhibitor is added. A saturating amount of the irreversible quantifiable MetAP-2 inhibitor is present when the addition of more irreversible quantifiable MetAP-2 inhibitor no longer results in an increase in the amount of MetAP-2/inhibitor complex formed. In a preferred embodiment, in the presence of a saturating amount of the irreversible quantifiable inhibitor, substantially all the free biological target in the sample is converted to target/inhibitor complex. For the operation of the inventive method, it is not necessary that every molecule of free biological target is converted to target/inhibitor complex, but the amount converted to the complex should be greater than the amount which remains free,

i.e., more than about 50% of the free biological target should be converted to target/inhibitor complex, preferably at least about 60%, more preferably at least about 75% and most preferably, at least about 90%.

Moreover, as evidenced by a plethora of issued U.S. patents containing this term in the issued claims (examples of which are attached herein as Appendices D and E²) this term was accepted by the U.S. Patent and Trademark Office to be clear and definite. Based on all of the foregoing, it is evident that the term “saturating amount” would be clear and definite to one of skill in the art based on the teachings in Applicants’ specification and the general knowledge in the art available at the time of the invention. Accordingly, Applicants respectfully request that this rejection of claims 3 and 7 under 35 U.S.C. §112, second paragraph be reconsidered and withdrawn.

The Examiner has further rejected claims 3 and 7 under 35 U.S.C. § 112, second paragraph, as allegedly “being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” In particular, the Examiner is of the opinion that

[i]t is unclear as to how much constitutes “substantially all of the free biological target reacts”.

Applicants respectfully traverse this rejection and submit that, based on the teachings in the specification and the knowledge generally available to one of skill in the art at the time of filing, the phrase “substantially all of the free biological target reacts” would be clear and definite to the skilled artisan. Once more, Applicants point the Examiner to, for example, page 9, line 28, through page 10, line 11 of the specification where Applicants expressly define a “saturating amount” and further teach that

in the presence of a saturating amount of the irreversible quantifiable inhibitor, substantially all the free biological target in the sample is converted to target/inhibitor complex. For the operation of the inventive method, it is not necessary that every

² See, e.g., claims 1, 5, 18, 21, 24, 27, 30, 33, 36, 39, and 42 of Appendix D and claims 19-21 of Appendix E.

molecule of free biological target is converted to target/inhibitor complex, but ***the amount converted to the complex should be greater than the amount which remains free, i.e., more than about 50% of the free biological target should be converted to target/inhibitor complex, preferably at least about 60%, more preferably at least about 75% and most preferably, at least about 90%.*** (Emphasis added).

Based on all of the foregoing, it is evident that, as recited in the claims, the phrase “substantially all of the free MetAP-2 reacts with the quantifiable irreversible Metap-2 inhibitor to form a MetAP-2/inhibitor complex” would be clear and definite to one of skill in the art. Accordingly, Applicants respectfully request that this rejection of claims 3 and 7 under 35 U.S.C. §112, second paragraph be reconsidered and withdrawn.

Rejection of Claims 1-17 Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-17 under 35 U.S.C. §103(a) as being unpatentable over Turk *et al.* ((1999) *Chem. Biol.* 6:823-833) in view of Soker *et al.* (US 2005/0112063). In particular, the Examiner is of the opinion that

Turk *et al.* (*Chem. Biol.* 1999, 6, 823-833) discloses the treatment of bovine aortic endothelial cells with fumagillin analog, TNP-470 that are then lysed for determination of unbound MetAP2. These lysates were treated with biotin-fumagillin, labeling MetAP2 protein that remained unbound following TNP-470 treatment. Bound biotin was detected by probing the membrane with streptavidin-horseradish peroxidase, and the signal was competed by cell treatment with increasing concentrations of TNP-470 (p824, results). The inhibition of MetAP2 was examined in several human cell lines, such as HeLa, Jurkat T lymphocytes and HT1081C (p825, paragraph 1). Turk *et al.* (*Chem. Biol.* 1999, 6, 823-833) does not teach of the administration of the fumagillin analog to a subject or removing biological samples from the subject.

Soker *et al.* discloses the method of measuring the ability of a test compound to inhibit a biological target via the administration of an antiangiogenic compound, such as a polymer conjugated TNP-470 to a subject *in vitro* or *in vivo* and assessing the bioeffectiveness of the compound (p2, [0014] and [0020]; p10, [0109]). The method of measuring the ability of the polymer conjugated TNP-470 to inhibit the formation of blood vessels is by measuring the level of protein in a biological sample, such as the

bodily fluid blood (p2, [0020]). The measurement of the sample after administration of the polymer conjugated TNP-470 is compared to a control sample taken prior to administration of the polymer conjugated TNP-470 (p2, [0020]). Also the effects of the polymer conjugated TNP-470 can be examined for the inhibition of liver regeneration compared to a control via hepatectomy (p3, [0029]; p9, [0100]; p10, [0106]).

At the time of the invention it would have been obvious to one ordinarily skilled in the art to use the method of measuring the inhibition of MetAP2, such as disclosed by Turk *et al.* by administering the fumagillin analog to a subject (*in vivo*) then collecting the blood and/or liver tissue samples and examining the samples for inhibition (Soker *et al.*). The use of the polymer conjugated TNP-470 is advantageous as the TNP-470 is not water-soluble but becomes water-soluble following conjugation with the polymer (Soker *et al.*, p10, [0103]).

With respect to claims 1-5 cancellation of these claims has rendered the Examiner's rejection moot. With respect to claims 6-17, Applicants respectfully traverse the Examiner's assertion that the proposed combination of the above-cited references would have rendered the claimed invention obvious to the ordinarily skilled artisan at the time of the invention for the following reasons. Claim 6, and claims dependent therefrom, are directed to methods for determining the extent of inactivation of MetAP-2 in a biological sample derived from a subject, comprising the steps of (a) administering a test compound which is an inhibitor of MetAP-2 to the subject, wherein any MetAP-2 in the body of the subject that reacts with the test compound is inactivated MetAP-2 and any MetAP-2 that does not react with the test compound is free MetAP-2, (b) ***removing a plurality of biological samples from the subject, wherein each of the plurality of biological samples is derived from a different tissue of the subject, and (c) determining the amount of free MetAP-2 within each of plurality of the biological samples,*** and (d) comparing the amounts determined in step (c) with the amount determined in a control sample, wherein a decrease in the amounts in each of the samples determined in step (c) compared to the amount in the control sample is a measure of the extent of inactivation of MetAP-2 in each of the biological samples.

The test for *prima facie* obviousness is consistent with the legal principles enunciated in *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). *Takeda Chem. Indus.*,

Ltd. v. Alpharma Pty., Ltd., 2007 U.S. App. LEXIS 15349, at *13 (Fed. Cir. 2007).

“While the KSR Court rejected a rigid application of the teaching, suggestion, or motivation (“TSM”) test, the Court acknowledged the importance of identifying ‘a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does’ in an obviousness determination. *Id.* at *13-14 (quoting KSR, 127 S. Ct. at 1731). Although the TSM test should not be applied in a rigid manner, it can provide helpful insight to an obviousness inquiry. *KSR*, 127 S. Ct. at 1731. ***Furthermore, the prior art reference (or references when combined) must teach or suggest all of the claim limitations (M.P.E.P. § 2143).***

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness, since the cited references, alone or in combination, fail to teach or suggest each element of the claimed methods. In particular, Turk *et al.* teach a method for determining the ability of a test compound to inactivate MetAP2 in cultured bovine aortic endothelial cells (BAECs) (page 824, right-hand column, second paragraph). However, there is no teaching or suggestion in Turk *et al.* to ***administer a test compound to a subject***, or removing a biological sample from the subject, as required the pending claims. Moreover, Turk *et al.* fail to teach or suggest ***removing a plurality of biological samples from the subject, wherein each of the plurality of biological samples is derived from a different tissue of the subject, or determining the amount of free MetAP-2 within each of plurality of the biological samples***, as required by the pending claims. Thus, Turk *et al.* fail to teach or suggest the claimed methods.

Moreover, the secondary reference relied on by the Examiner, Soker *et al.*, does not make up for the deficiencies in the primary reference. Specifically, Soker *et al.* teach methods for decreasing vascular hyperpermeability by administering an anti-angiogenic compound to a subject treated with a permeability inducing agent. Soker *et al.* teach that bioeffectiveness of an anti-angiogenic compound may be assessed by determining the amount of a protein in a ***single bodily fluid*** derived from a subject (see, e.g., page 2, [0020] of Soker *et al.*). Soker *et al.* also teach that the bioeffectiveness of an anti-angiogenic compound on endothelial cell proliferation may be assessed by observing liver regeneration in mice receiving a 2/3 hepatectomy (see, e.g., page 9, [0100] and page 10, [[0106])). However, ***Soker et al. fail to teach or suggest that the excised liver may be, or***

is used, to determine the amount of free anti-angiogenic compound in the single biological sample or that a plurality of biological samples are removed from the subject, wherein each of the plurality of biological samples is derived from a different tissue of the subject. Thus, Soker *et al.* also fail to teach or suggest the claimed methods.

In view of the foregoing, it is evident that, Turk *et al.* and/or Soker *et al.*, either alone or in combination, fail to teach or suggest each element of the claimed invention and, thus, fail to render the claimed invention obvious. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

The Examiner has also rejected claims 1-17 under 35 U.S.C. §103(a) as allegedly being obvious over Griffiths, *et al.* ((1998) *Proc. Natl. Acad. Sci., USA* 95:15183-15188) in view of Soker *et al.* (US 2005/0112063). Specifically, the Examiner is of the opinion that

Griffiths *et al.* (*Proc. Natl. Acad. Sci.* 1998, 95, 15183-15188) discloses the incubation of recombinant human MetAP2 with ovalicin followed by incubation with fluorescein-fumagillin analog. The samples were dialyzed, alkylated, digested and subjected to HPLC separation. The absorbance of each eluate was monitored and the fractions corresponding to peaks for the binding of the fluorescein-fumagillin analog to the MetAP2 were collected (p15184, identification of the covalently modified MetAP2 residue by using fluorescein-fumagillin). It is disclosed that fumagillin and ovalicin covalently bind and inhibit MetPA2 (abstract). Griffiths *et al.* (*Proc. Nati Acad. Sci.* 1998, 95, 15183-15188) does not disclose the administration of ovalicin, a fumagillin analog to a subject or removal of a biological sample from a subject.

Soker *et al.* (US 2005/0112063A1) discloses the method of measuring the ability of a test compound to inhibit a biological target via the administration of an antiangiogenic compound, such as a polymer conjugated TNP-470 to a subject *in vitro* or *in vivo* and assessing the bioeffectiveness of the compound as well as that stated above.

At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize the method to identify the binding/inhibition of MetAP2 to/by a quantifiable irreversible inhibitor, such as fluorescein-fumagillin, Griffiths *et al.* by administering the fumagillin analog to a subject (*in vivo*) then

collecting the blood and/or liver tissue samples and examining the samples for inhibition (Soker *et al.*). The use of the polymer conjugated TNP-470 is advantageous as the TNP-470 is not water-soluble but becomes water-soluble following conjugation with the polymer (Soker *et al.*, p10, [0103]).

With respect to claims 1-5 cancellation of these claims has rendered the Examiner's rejection moot. With respect to claims 6-17, Applicants respectfully traverse the Examiner's assertion that the proposed combination of the above-cited references would have rendered the claimed invention obvious to the ordinarily skilled artisan at the time of the invention for the following reasons. Claim 6, and claims dependent therefrom, are directed to methods for determining the extent of inactivation of MetAP-2 in a biological sample derived from a subject, comprising the steps of (a) administering a test compound which is an inhibitor of MetAP-2 to the subject, wherein any MetAP-2 in the body of the subject that reacts with the test compound is inactivated MetAP-2 and any MetAP-2 that does not react with the test compound is free MetAP-2, (b) ***removing a plurality of biological samples from the subject, wherein each of the plurality of biological samples is derived from a different tissue of the subject, and (c) determining the amount of free MetAP-2 within each of plurality of the biological samples,*** and (d) comparing the amounts determined in step (c) with the amount determined in a control sample, wherein a decrease in the amounts in each of the samples determined in step (c) compared to the amount in the control sample is a measure of the extent of inactivation of MetAP-2 in each of the biological samples.

As discussed above, the test for *prima facie* obviousness is consistent with the legal principles enunciated in *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). *Takeda Chem. Indus., Ltd. v. Alpharma Pty., Ltd.*, 2007 U.S. App. LEXIS 15349, at *13 (Fed. Cir. 2007). "While the KSR Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test, the Court acknowledged the importance of identifying 'a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' in an obviousness determination. *Id.* at *13-14 (quoting KSR, 127 S. Ct. at 1731). Although the TSM test should not be applied in a rigid manner, it can provide helpful insight to an obviousness inquiry. *KSR*,

127 S. Ct. at 1731. ***Furthermore, the prior art reference (or references when combined) must teach or suggest all of the claim limitations (M.P.E.P. § 2143).***

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness, since the cited references, alone or in combination, fail to teach or suggest each element of the claimed methods. More specifically, as previously argued, the primary reference relied upon by the Examiner, Griffiths *et al.*, teaches an *in vitro* assay to detect binding of MetAP2 to a fumagillin analog. However, Griffiths *et al.* fail to teach or suggest ***an in vivo assay or removing a plurality of biological samples from the subject, wherein each of the plurality of biological samples is derived from a different tissue of the subject, or determining the amount of free MetAP-2 within each of plurality of the biological samples***, as required by Applicants' claims. Thus, Griffiths, *et al.* fail to teach or suggest the claimed methods.

The teachings of Soker *et al.* fail to make up for the deficiencies of Griffiths *et al.* in that Soker *et al.* fail to teach or suggest ***removing a plurality of biological samples from the subject, wherein each of the plurality of biological samples is derived from a different tissue of the subject, or determining the amount of free MetAP-2 within each of plurality of the biological samples***. Rather, Soker *et al.* teach methods for decreasing vascular hyperpermeability by administering an anti-angiogenic compound to a subject treated with a permeability inducing agent. Soker *et al.* teach that bioeffectiveness of an anti-angiogenic compound may be assessed by determining the amount of a protein in a ***single bodily fluid*** derived from a subject (see, e.g., page 2, [0020] of Soker *et al.*). Soker *et al.* also teach that the bioeffectiveness of an anti-angiogenic compound on endothelial cell proliferation may be assessed by observing liver regeneration in mice receiving a 2/3 hepatectomy (see, e.g., page 9, [0100] and page 10, [[0106])). However, ***Soker et al. fail to teach or suggest that the excised liver may be, or is used, to determine the amount of free anti-angiogenic compound in the single biological sample or that a plurality of biological samples are removed from the subject, wherein each of the plurality of biological samples is derived from a different tissue of the subject***. Thus, Soker *et al.* also fail to teach or suggest the claimed methods.

In view of the foregoing, it is evident that, Griffiths *et al.* and/or Soker *et al.*, either alone or in combination, fail to teach or suggest the claimed invention and, thus,

fail to render the claimed invention obvious. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.


SUMMARY

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicants' Attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

The Commissioner is hereby authorized to charge any fees associated with the filing of this communication to our Deposit Account No. 12-0080, under Order No. PPI-144 from which the undersigned is authorized to draw.

Dated: November 16, 2007

Respectfully submitted,

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APPENDIX A



Wake up to skin
that's as resilient as you are.



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portion

2 entries found.

portion[1,noun]

portion[2,transitive verb]

Main Entry: **¹portion** ◀

Pronunciation: \pôr-shən\

Function: *noun*

Etymology: Middle English *porcioun*, from Anglo-French, from Latin *portion-*, *portio*; akin to Latin *part-*, *pars* part

Date: 14th century

1 : an individual's part or share of something: as **a** : a share received by gift or inheritance **b** : **DOWRY** **c** : enough food especially of one kind to serve one person at one meal

2 : an individual's lot, fate, or fortune : one's share of good and evil

3 : an often limited part of a whole

synonyms see [PART](#), [FATE](#)

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